K024245

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Date: 14 March, 2004

Topic: **510(k) Safety and Effectiveness Summary as per 21 CFR Section 807.92(c)**
**Envoy Patient Monitor - new EEG module:**

To: Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk
From: Asher Kassel, Director of Regulatory Affairs

**Establishment Name, Registration Number and Address:**

| | |
|---|---|
| Name: | Mennen Medical Ltd. |
| Registration Number | 9611022 |
| Operator Number: | 9011766 |
| Address: | 4 Hayarden Street, Yavne, 81228, Israel |
| Postal Address: | PO Box 102,<br>Rehovot, 76100, Israel |
| Tel: +972-8-9323333<br>Fax: +972-8-9328510 | |
| Contact person: | Asher Kassel, Director of Regulatory Affairs |

**Product Name:**
Proprietary: ENVOY
Common: Physiological Patient Monitor
Mennen Medical Part Number: 550-010-000 (full system)
554-000-010 (CPU only)

New Envoy EEG module P/N: 551-138-000

**FDA Classification of Envoy Patient Monitor:**

| | |
|---|---|
| Classification Name: | Arrhythmia Detector and Alarm |
| Classification Number: | 21 CFR 870.1025 |
| Classification: | Class III |
| Product Code: | 74 DSI |

**FDA Classification of new Envoy EEG module:**

| | |
|---|---|
| Classification Name: | Electroencephalograph |
| Classification Number: | 21 CFR 882.1400 |
| Classification: | Class II |
| Product Code: | OMC |

**Performance Standards:**

None promulgated

**Voluntary Standards:**

***IEC 60601-1:**
General Requirements for Safety for Medical Electrical Systems - part 1, (1988);
Amendment 1 – 1991-11;
Amendment 2 – 1995-03

***IEC 60601-1-2:**
General Requirements for Safety
Collateral Standard: Electromagnetic compatibility - Requirements and tests.

***IEC 60601-2-26:**
Particular Requirements for the safety of electroencephalographs

**Predicate Device:**

EEG module of the Mennen Medical Horizon 2000 patient monitor (K910945)

**Intended Use and Device Description of the Envoy Patient Monitor:**

The Envoy is intended for use as a multiparameter physiological patient monitoring system for the monitoring and recording of patient information or any in-hospital application that requires patient monitoring. The Envoy can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure, $eTCO_2$, and EEG.

Functions include display of multiparameter waveforms, vital signs, alarm & status messages. This effectively allows the Envoy to monitor a wide-range of adult, pediatric, and neonatal patient conditions, in many different areas of the hospital.
The Envoy consists of a main processing unit, a mountable color monitor, and a module rack housing the various Mennen Medical plug-in *vital signs* modules. The modules monitor the patient's vital signs. The vital sign data derived from the modules by the Envoy are presented on the monitor as waveform and numeric displays.

The Envoy vital signs modules acquire vital signs data from the patient; the modules display the patient waveforms, vital signs information, and alarms indications on the Envoy display unit.

The Envoy is not a life supporting, nor life-sustaining device; nor is it implantable; therefore sterility is not a consideration. The Envoy is not a kit and does not contain any drug or biological products.

**Intended Use and Functional Description and of the Envoy EEG module:**

The Envoy EEG module can monitor up to 4 differential EEG channels and display processed trend and real-time EEG waveforms. EEG monitoring is continuous and in real time. The Envoy EEG module does not have derived parameters such as Aspect BIS or other derived parameters. The Envoy EEG module can be used as an indicator of brain damage or cerebral activity. The EEG module is commonly used to monitor the cerebral activity of patients who have suffered serious head injury or to evaluate the state of consciousness of a patient.

The **EEG** module of the Envoy patient monitor is not sold as a stand-alone EEG device, but as part of a multiparameter physiological patient monitoring system (**Envoy**).
In Chapter 1 of the Envoy Operating Manual, the following **Prescription Notice** appears: "Federal United States law restricts the sale and use of this instrument to qualified medical personnel only."

The primary purpose of the **EEG** module is to determine the need for more detailed EEG recordings. The EEG module is not a replacement for a comprehensive multi-channel (16 to 36 or more) EEG diagnosis by a neurology specialist. Since four channels are displayed simultaneously, qualitative assessments can be made regarding right and left hemispheric activity.

*Note: The EEG module is not intended for use on infants.*

The EEG module of the Envoy monitor consists of the following main parts/components:

- 5 lead input cable
- Four channel differential amplifier
- Processing and Storage circuit block (P&SB)

The P&SB of the EEG module is identical to the Mennen Medical P&S Boards located in the other Envoy input modules. The P&SB consists of a communications processor and memory, and performs local data storage and protocol translation from low-level protocol to high level protocol. The Envoy can display between one and four EEG channels on and the user can control the sensitivity and the frequency response of the EEG waveforms. Both sensitivity and filters are common to all four channels. The top displayed EEG channel is stored in Overview for up to 72 hours.

**Summary of the technological characteristics of the new Envoy EEG module** (incorporating Mennen Medical proprietary technology):

| **Envoy EEG module** | |
|---|---|
| **Part Number:** | 551-138-000 |
| **Module size:** | **Single slot**<br>Height: 10.0cm (4.0 in)<br>Width: 4.0 cm (1.6 in)<br>Depth: 14.0 cm (5.5 in) |

| **Monitored Parameters and Features** | **Mennen Medical Envoy EEG module** |
|---|---|
| Part/Option Number | 551-138-000 |
| EEG channels | 4 differential channels |
| Gain Selection/ Sensitivity Control | Selects one of 10 possible gains:<br>10, 20, 50, 70, 100, 200, μVolt/cm and<br>½ ,1, 2, 4 mVolt/cm |
| Common Mode Rejection Ratio | 100 dB at 50/60 Hz (5 KΩ imbalance) |
| Frequency Response selection | 0.5 Hz to 75 Hz (-3db) |
| Noise | < 0.4μ V rms, 0.5 to 30Hz<br>< 2.5μ V rms, 30 to 70Hz |
| Input Range | 1.0 mV p-p full scale |
| Input Impedance | 0.5 M Ohm |
| Input Resolution | 70 nV p-p minimum |
| Linearity | ±2% |
| DC input offset ± | ± 320 mV maximum |
| Bias Current: | Less than 7 nA per input (each electrode may be connected to more than one input) |

| Monitored Parameters and Features | Mennen Medical Envoy EEG module |
|---|---|
| Low filter (High pass)<br>High filter (Low pass) | 0.5 - 1.5 Hz<br>15 - 35 - 50 - 70 Hz |
| Sampling rate: | at least 600 Hz per channel |
| Anti-Aliasing Filter: | EEG stopband 77 - 80 Hz dB |
| Maximum sensitivity: | 0.5 µVolt/mm |
| Sensitivity control: | 1 - 2 - 3 - 5 - 7 - 10 - 15 - 20 - 30 - 50 - 70 µVolt/mm or mVolt/cm |
| Defibrillation Protection | 400 Joule |
| Degree of protection against electrical shock | Type BF Applied part |
| Electro-surgery | EEG waveform returns to normal within 5 seconds from cessation of ESU operation |

| Displayed Parameters | Mennen Medical Envoy EEG module |
|---|---|
| EEG waveforms | 4 channels |

| Display Functions | Mennen Medical Envoy EEG module |
|---|---|
| Channel selection | Yes – 1 to 4 channels |

| | Mennen Medical Envoy EEG module |
|---|---|
| Waveform Selection | A-B; B-C; C-D; D-E |
| EEG Cable | 5 Leads (4 differential channels).<br>Leads marked as A, B, C. D and E. |
| Error Message | Cable out |

**Conclusion of comparison of technological characteristics:**

We consider the Envoy EEG module to be substantially equivalent to the EEG module of the Mennen Medical Horizon 2000 patient monitor (K910945) and we submit that the differences between the two modules do not raise any new issues of safety and effectiveness

**Testing**

The Envoy EEG module has been subject to extensive safety and performance testing. Final testing for the system included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Safety testing and EMC testing were performed by an independent testing laboratory to ensure that the device complies to applicable industry and safety standards.

Signature:

A. Kassel

Asher Kassel,
Director of Regulatory Affairs,
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Asher Kassel
Director of Regulatory Affairs
Mennen Medical Ltd.
P.O. Box 102
Rehovot, 76100, Israel

APR - 9 2012

Re: K024245
Trade/Device Name: Envoy Patient Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMC
Dated (Date on orig SE ltr): April 18, 2004
Received (Date on orig SE ltr): April 29, 2004

Dear Mr. Kassel:

This letter corrects our substantially equivalent letter of May 10, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K024245

Device Name: Envoy Patient Monitor

**Indications For Use:**

The Envoy is intended for use as a multiparameter monitoring system.

The Envoy can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure, EtCO2 and EEG.
The EEG module is not intended for use on infants.

This effectively allows the Envoy to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital. Functions include display of multiparameter waveforms, vital signs, alarm & status messages.

The Mennen Medical Envoy is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring. The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K024245